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NON-PROVISIONAL UTILITY APPLICATION TRANSMITTAL LETTER Atty. Docket No: 00.EMT 34(c).US (E1067/20007)

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

jc874 U.S. PTO
07/17/00

jc682 U.S. PTO
09/617340
07/17/00

Sir:

Transmitted herewith for filing under 35 U.S.C. §111 and 37 CFR §1.53(b) is a Continuation of prior Application No.: 09/176,439, filed October 21, 1998, which claims the benefit of U.S. Provisional Application No. 08/956,237 (regular application converted to provisional on October 20, 1998). This is not a CPA, and we request a new application number. Please do not abandon the parent application.

INVENTOR(S): Joseph Gross, Gilad Lavi and Izrail Tsals
FILED: July 17, 2000
ENTITLED: AN IMPROVED AUTOMATIC SYRINGE

Enclosed are:

- ☒ 21 pages of written description, claims and abstract.
- ☒ 6 sheet(s) of drawings.
- ☐ an assignment of the invention to _____.
- ☒ copy of executed declaration filed in prior application.
- ☐ ____ certified cop(ies) of a _____ application.
- ☒ power of attorney by assignee (original).
- ☐ a verified statement by the inventor(s) to establish small entity status under 37 CFR §§1.9 and 1.27
- ☐ a verified statement by the assignee(s) to establish small entity status under 37 CFR §§1.9 and 1.27
- ☒ information disclosure statement and PTO Form 1449.
- ☒ preliminary amendment.
- ☒ other: Return receipt postcard (MPEP 503)

The prior application is assigned to Élan Corporation, plc. by virtue of Assignment recorded at reel 9724, frame 0621.

The filing fee has been calculated, less any claims cancelled and including any claims added by the Preliminary Amendment, as shown below:

FOR:	NO. FILED	NO. EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE		OTHER THAN A SMALL ENTITY RATE	OTHER THAN A SMALL ENTITY FEE
BASIC FEE				$ 345	OR		$ 690
TOTAL CLAIMS	54 - 20	= 34	x 9 =	$	OR	x 18	$ 612
INDEP CLAIMS	9 - 3	= 6	x 39 =	$	OR	x 78	$ 468
MULTIPLE DEPENDENT CLAIMS PRESENTED			+ 130 =	$	OR	+ 260	$
			TOTAL	$	OR	TOTAL	$1,770

* If the difference is less than zero, enter "0".

☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. 03-0075 as described below. A duplicate copy of this sheet is enclosed.

- ☒ Charge the amount of $ 1,770 as filing fee.
- ☒ Charge payment of any additional filing fees required under 37 C.F.R. §§1.16 and 1.17 or credit any overpayment to Deposit Account No 03-0075.

Respectfully submitted,

July 17, 2000

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

Applicants	:	Joseph Gross, Gilad Lavi and Izrail Tsals
Serial No.	:	Continuation Application of ASN: 09/176,439 filed on October 21, 1998
Filed	:	July 17, 2000
For	:	AN IMPROVED AUTOMATIC SYRINGE
Group Art Unit	:	3763
Examiner	:	Michael Hayes

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to initial examination of this continuation application filed under 35 C.F.R. 1.53(b), please amend this application in the following manner:

IN THE SPECIFICATION:

On page 2, immediately after the heading "BACKGROUND OF THE INVENTION" insert the sentence - - This application is a continuation of U.S. Application No. 09/176,439, filed on October 21, 1998, entitled An Improved Automatic Syringe, which claims the benefit of U.S. Provisional Application No. 08/956,237 (regular application converted to provisional on October 20, 1998), which is assigned to the same assignee as this invention, and whose disclosure is incorporated by reference herein. - -

IN THE CLAIMS:

Please cancel claims 1-28 from this continuation application only.

Please add the following claims 29-82.

What is claimed is:

29. A syringe comprising:

a barrel having a liquid drug reservoir therein, the barrel having a first end and a second end, the drug reservoir having a piston slidingly engaged therein;

a needle assembly mounted at the first end of the barrel, the needle assembly holding a needle;

a nozzle sleeve moveably mounted on the first end of the barrel from a first position where the tip of the needle is concealed by the nozzle sleeve to a second position where the tip of the needle is exposed, to an activation position, wherein when the nozzle sleeve is initially pressed against an injection site, the nozzle sleeve moves from the first position to the second position, and the tip of the needle penetrates the injection site, and when the sleeve moves from the second position to the activation position, the piston drives a liquid from the reservoir into the injection site through the needle.

30. The syringe of claim 29, further comprising an energizing source located at the second end of the barrel; the energizing source in communication with the reservoir when the energizing source is activated to push the piston to drive the liquid.

31. The syringe of claim 30, wherein the energizing source is a gas generator.

32. The syringe of claim 31, wherein the gas generator includes a first chamber containing a citric acid solution and a second chamber containing a sodium bicarbonate solution.

33. The syringe of claim 31, wherein the gas generator includes a first chamber containing a carbon dioxide solution and a second chamber containing dry ice pellets.

34. The syringe of claim 30, further comprising an actuator extending adjacent to and in communication with the energizing source, the actuator activating the energy source to push the piston.

35. The syringe of claim 29, further comprising a flexible retractor located between the needle assembly and the nozzle sleeve, the flexible retractor biasing the nozzle sleeve to the first position.

36. The syringe of claim 35, wherein the retractor is a helical compression spring.

37. The syringe of claim 29, wherein the nozzle sleeve moves axially and rotationally relative to the barrel between the first position and the second position.

38. The syringe of claim 37, wherein the nozzle sleeve further includes a channel extending along an exterior wall of the sleeve, and the barrel further includes a peg extending inward from an inner wall of the barrel, the channel receiving the peg to cause relative rotational movement during relative axial movement between the barrel and sleeve, and having a shape that maintains the sleeve in a locked position to prevent further exposure of the needle after extraction of the fluid.

39. The syringe of claim 29, further comprises a needle cover frictionally engaged about the needle assembly to cover and protect the tip of the needle from contact.

40. A method of injecting liquid drug, comprising:

a) providing a barrel having a liquid drug reservoir therein and a delivery needle mounted on a first end of the barrel,

b) moveably mounting a sleeve within the first end of the barrel, the sleeve capable of assuming a first position where the tip of the needle is concealed by the sleeve, a second position where the tip of the needle is revealed, and a third position where the liquid drug is pushed from the liquid drug reservoir through the delivery needle;

c) pressing the sleeve against an injection site such that the sleeve moves from the first position to the second position and the tip of the needle penetrates the injection site; and

d) moving the sleeve to the third position to drive the liquid from the reservoir into the injection site through the delivery needle.

41. The method of claim 40, after step a), further comprising locating an energizing source at a second end of the barrel, the energizing source in communication with the reservoir for pushing a plunger to drive the liquid when the sleeve is in the third position.

42. The method of claim 41, wherein the energizing source includes a gas generator having first and second chambers, and further comprising mixing a first solution in the first chamber with a second solution in the second chamber when the sleeve is in the third position to create a force that pushes the plunger to drive the liquid.

43. The method of claim 42, wherein the first solution includes citric acid and the second solution includes sodium bicarbonate.

44. The method of claim 42, wherein the first solution includes carbon dioxide and the second solution includes dry ice pellets.

45. The method of claim 40, further comprising biasing the sleeve to the first position.

46. The method of claim 40, further comprising moving the sleeve axially and rotationally relative to the barrel between the first position and the second position.

47. A syringe comprising:

a barrel having a liquid drug reservoir therein, the barrel having a first end and a second end;

a delivery needle mounted on the first end of the barrel;

an energizing source located at the second end of the barrel; the energizing source in communication with the reservoir when the energizing source is activated;

an actuator extending adjacent to and in communication with the energizing source; and

a sleeve moveably mounted on the first end of the barrel from a first position where the tip of the needle is concealed by the sleeve to a second position where the tip of the needle is exposed, to an activation position, wherein

when the sleeve is initially pressed against an injection site, the sleeve moves from the first position to the second position, and the tip of the needle penetrates the injection site, and

when the sleeve moves from the second position to the activation position, the actuator activates the energizing source which drives a liquid from the reservoir into the injection site through the needle.

48. The syringe of claim 47, wherein the energizing source is a gas generator.

49. The syringe of claim 48, wherein the gas generator includes a first chamber containing a citric acid solution and a second chamber containing a sodium bicarbonate solution.

50. The syringe of claim 48, wherein the gas generator includes a first chamber containing a carbon dioxide solution and a second chamber containing dry ice pellets.

51. The syringe of claim 47, further comprising a flexible retractor located between the needle assembly and the nozzle sleeve, the flexible retractor biasing the nozzle sleeve to the first position.

52. The syringe of claim 51, wherein the retractor is a helical compression spring.

53. The syringe of claim 47, wherein the nozzle sleeve moves axially and rotationally relative to the barrel between the first position and the second position.

54. The syringe of claim 53, wherein the nozzle sleeve further includes a channel extending along an exterior wall of the sleeve, and the barrel further includes a peg extending

inward from an inner wall of the barrel, the channel receiving the peg to cause relative rotational movement during relative axial movement between the barrel and sleeve.

55. A method of injecting liquid drug, comprising:

a) providing a barrel having liquid drug reservoir therein and a delivery needle mounted on a first end of the barrel;

b) locating an energizing source at the second end of the barrel, the energizing source in communication with the reservoir when the energizing source is activated;

c) moveably mounting a sleeve within the first end of the barrel, the sleeve capable of assuming a first position where the tip of the needle is concealed by the sleeve, a second position where the tip of the needle is revealed, and an activation position;

d) placing the sleeve against an injection site;

e) moving the barrel toward the injection site, thereby causing the sleeve to move from the first position to the second position and the tip of the needle to penetrate the injection site; and

f) moving the sleeve to the activation position to activate the energizing source to drive a liquid from the reservoir into the injection site through the needle.

56. The method of claim 55, wherein the energizing source includes a gas generator having first and second chambers, and further comprising mixing a first solution in the first chamber with a second solution in the second chamber when the sleeve is in the third position to create a force that pushes the plunger to drive the liquid.

57. The method of claim 56, wherein the first solution includes citric acid and the second solution includes sodium bicarbonate.

58. The method of claim 56, wherein the first solution includes carbon dioxide and the second solution includes dry ice pellets.

59. The method of claim 55, further comprising biasing the sleeve to the first position.

60. The method of claim 55, further comprising moving the sleeve axially and rotationally relative to the barrel between the first position and the second position.

61. A syringe comprising:

a member having a liquid drug reservoir therein, the member having a first end and a second end;

a delivery needle mounted on the first end of the member;

an energizing source located at the second end of the member, the energizing source in communication with the reservoir when the energizing source is activated; and

a sleeve moveably mounted on the first end of the member from a first position where the tip of the needle is enclosed by the sleeve, to a second position where the tip of the needle is enclosed by the sleeve, to a second position where the tip of the needle is exposed, to a third position where the sleeve activates the energizing source, wherein

when the sleeve is initially pressed against an injection site, the sleeve moves from the first position to the second position such that the tip of the needle penetrates the injection site,

and when the sleeve moves from the second position to the third position, the energizing source drives a liquid from the reservoir into the injection site through the needle.

62. A method of injecting liquid drug, comprising:

a) providing a member having a liquid drug reservoir therein and a delivery needle mounted on a first end of the member,

b) locating an energizing source at the second end of the member, the energizing source in communication with the reservoir when the energizing source is activated;

c) moveably mounting a sleeve within the first end of the member, the sleeve capable of assuming a first position where the tip of the needle is concealed by the sleeve, a second position where the tip of the needle is revealed, and a third position where the energizing source is activated;

d) pressing the sleeve against an injection site such that the sleeve moves from the first position to the second position and the tip of the needle penetrates the injection site; and

e) moving the sleeve to the third position to activate the energizing source to drive the liquid from the reservoir into the injection site through the needle.

63. An injection device comprising a housing, a nozzle assembly defining a fluid chamber, having an opening for slidingly receiving at least a portion of the needle and being removably associated with the housing, a plunger movable in the fluid chamber, a trigger assembly, a force generating source operatively associated with the trigger assembly so that movement of the trigger assembly activates the energy source to move the plunger in a first

direction to expel a fluid from the fluid chamber, and a retractable injection-assisting needle at a distal end of the injector, said retractable injection-assisting needle comprising:

a needle tip located at a distal end of the needle with at least a portion configured and dimensioned to slide through the nozzle assembly opening;

a discharge channel within the needle tip and terminating in an orifice through which the fluid is expelled;

a body portion to direct fluid towards the discharge channel;

a plunger receptor configured and dimensioned to receive at least a portion of the plunger; and

a retraction element operatively associated with the nozzle assembly;

wherein the needle is located within the nozzle assembly in a retracted position prior to activation of the energy source; movement of the plunger in the first direction upon activation of the energy source results in at least a portion of the needle tip extending beyond the nozzle assembly opening; and the retraction element returns the needle tip to the retracted position after activation of the energy source.

64. The injection device of claim 63, wherein the retraction element moves to allow extension of the needle tip beyond the nozzle assembly opening and then returns to its original position to return the needle tip to its retracted position.

65. The injection device of Claim 64, wherein the retraction element is a spring.

66. The injection device of claim 63, wherein the needle body has an exterior surface which includes a ridge or recess for accommodating the retraction element.

67. The injection device of claim 63, wherein a shoulder is disposed between the needle tip and the needle body for accommodating the retraction element.

68. The injection device of claim 63, wherein the needle tip, when extended, has a length of approximately one to three (1-3) mm.

69. An injection device comprising:

a housing having distal and proximal ends;

a fluid chamber located within said housing for holding a medicament;

an injection-assisting needle located in the distal end of said housing for delivering fluid from the fluid chamber;

a plunger movable within the fluid chamber;

a force generating source capable of providing sufficient force on the plunger to eject the medicament from the fluid chamber;

a needle guard located at the distal end of said housing for concealing said needle, the needle guard being moveable between a protecting position and an injecting position; and

an activation element operatively associated with the needle guard,

wherein retraction of the needle guard from the protecting position to the injecting position exposes the needle so that activation of the force generating source moves the plunger to expel medicament from said fluid chamber and thereby eject the medicament.

70. The injection device of claim 69, wherein retraction of the needle guard from the protecting position to the injecting position activates the force generating source and the force generating source provides sufficient force to eject the medicament in about three to five (3-5) seconds.

71. The injection device of claim 70, further comprising a locking element associated with the needle guard for locking the needle guard in the protecting position after activation of the injection device and after return of said needle guard to the protecting position.

72. The injection device of claim 69, wherein the needle is mounted on a needle holder operatively associated with the needle and the distal end of the housing, such that rotation of the needle holder places the needle in fluid communication with the fluid chamber.

73. The injection device of claim 69, further comprising a removable safety cap operatively associated with the distal end of the injection device such that rotation of the safety cap imparts rotation on the needle.

74. The injection device of claim 69, wherein the needle has a tip with a length of at least one to three (1-3) mm and the medicament is ejected at a at a pressure of about two atmospheres.

75. The injection device of claim 69,wherein at least a portion of the housing is made of a transparent or translucent material for allowing viewing of the fluid chamber.

76. The injection device of claim 69, wherein said fluid chamber comprises:

an ampule having a distal end, a proximal end and an opening in each of the distal and proximal ends;

a pierceable seal associated with the opening in the distal end; and

a stopper located in the proximal end of the ampule for maintaining the medicament inside the ampule.

77. The injection device of claim 76, wherein activation of the force generating source moves the pierceable seal towards the injection assisting needle to pierce the seal and moves the stopper to eject medicament from the injection assisting needle.

78. A method of delivering medicament to an injection site of a patient, comprising:

extending a needle from a shield prior to inserting the needle into the needle insertion point, said shield initially concealing the needle;

inserting the needle into the needle insertion point to a depth of about one to three (1-3) mm, with the needle being in fluid communication with a fluid chamber that contains the medicament; and

applying a force sufficient to eject the medicament from the fluid chamber and through the needle to deliver the medicament to the injection site,

wherein the needle insertion point is located more superficial than the injection site.

79. The method of claim 78, wherein the medicament is delivered in about three to five (3-5) seconds.

80. The method of claim 78, further comprising the step of retracting the needle into the shield after the desired amount of medicament has been delivered to the injection site.

81. The method of claim 78, wherein pressing the shield against the injection site causes activation of the energy mechanism.

82. The method of claim 78, wherein the needle has a length of approximately one to three (1-3) mm and the medicament is ejected at a pressure of about two atmospheres.

REMARKS

Claims 29-82 are pending. This Preliminary Amendment cancels claims 1-28, amends the specification and adds claims 29-82 to place this application in better condition for initial examination and allowance. No new matter is added.

Substantive examination and allowance of the application in due course are respectfully solicited.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

July 17, 2000

By ____________________

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An improved automatic syringe

This invention relates to automatic syringes, particularly for the delivery of drugs and other substances to human and animal subjects.

The problems associated with conventional syringes arise from the fact that they are unsuitable for use by untrained users. They are liable to cause injury and infection if not disposed of correctly, are available for re-use by drug addicts if not disposed of properly, and they are painful to the patient if not used correctly. Many patients are "needlephobic" and thus are extremely reluctant to use syringes regardless of the objective pain caused by a syringe even when used correctly.

In order to combat user compliance problems due to a fear of needles, a number of needleless syringe designs have been proposed. Such syringes deliver a drug to the subject by forcing the drug through the skin of the subject under air pressure.

The pressure required for such delivery is quite high - of the order of 6 atmospheres (approximately 600 kPa). This in itself gives rise to problems, since it leads to vials being broken occasionally under high pressure. It also means that the syringe must be primed before use, since a pre-filled ready-to-use syringe cannot be stored under such high pressure over a shelf life of months or years. Thus, the user or a physician or nurse is required to prepare the syringe before it can be used, which detracts from its attractiveness for self-administration.

A further problem which arises in needleless delivery is that the high pressure is primarily required to drive the drug through the *stratum corneum* layer of the skin. Underlying layers of the skin, and the subcutaneous tissue itself present relatively little resistance to the passage of the high-velocity powder. Because different patients have different skin types and thicknesses, and because the thickness and penetrability of the skin varies widely over a single patient's body, the level of the needleless

syringe delivery pressure must be regulated to drive the drug correctly past the *stratum corneum.*

A failure to correctly regulate the level of the driving pressure may result in an incorrect level of delivery due to insufficient levels of drug passing the *stratum corneum*, or due to the drug being delivered past the target tissue to the wrong type of tissue. For example if the delivery pressure is too high the drug may be delivered to the bone surface underlying the delivery region.

A further problem with needleless syringes is that they are considerably more bulky than conventional syringes due to the complex delivery mechanism and the thickness of walls required to contain the pressurised gas.

Alternative drug delivery devices are known which correctly deliver the drug in an automatic fashion but have certain disadvantages when compared to syringes. For example, our own WO-A-97/21457 discloses a drug delivery device containing a reservoir in communication with a needle, and a gas generator adapted to drive a medicament from the reservoir to the subject *via* the needle.

The device of WO-A-97/21457 is adapted to be affixed to the skin by an adhesive coating (covered before use by a release liner). When attached to the skin and actuated, delivery is automatic. After completion of delivery, the device is pulled away from the skin, causing the needle to be concealed by means of a displaceable cover, before the device is disposed of.

The device disclosed in WO-A-97/21457 is bulkier than that of a syringe which would deliver the same volume of drug, due to the configuration of the housing and the displaceable cover, which must provide a surface of sufficient surface area to be attached to the skin.

Additionally, when compared with a syringe, more steps are involved in effecting a suitable injection with the device disclosed in WO-A-97/21457 (for example, the release liner must be peeled away before the device can be operated). This makes the device less attractive to patients in need of an immediate injection because of the longer time needed to administer individual injections.

The above-mentioned prior art device while simpler than a needleless injector, is still somewhat complex as regards the automatic actuation of the gas generator and the locking snap mechanism which ensures that the needle is properly concealed by the displaceable cover before and after use. Added complexity results in higher costs and a greater possibility of device malfunction.

The present invention aims to overcome these and other disadvantages of the prior art and provide a syringe which is preferable to conventional syringes as well as to needleless injectors or automatic infusion pumps.

The invention provides a syringe comprising:

a) a barrel having a liquid drug reservoir therein;

b) a delivery needle mounted on the first end of the barrel;

c) a gas generator located at the second end of the barrel, the gas generator in communication with the reservoir when the gas generator is activated, so as to drive a liquid from the reservoir through the needle;

d) gas generation activation means; and

e) a sleeve resiliently mounted on the first end of the barrel between a first position where the tip of the needle is concealed by the sleeve to a second position where the tip of the needle is revealed,

f) whereby when the sleeve is placed against an injection site and the barrel is moved toward the injection site, the sleeve is caused to move from the first position to the second position, and the needle is caused to penetrate the injection site, such that

activation of the gas generator drives a liquid from the reservoir into the injection site through the needle.

The syringe according to the present invention addresses the problems associated with conventional syringes in a number of respects. Firstly, it causes the needle to be deployed automatically and the gas generator to be actuated automatically by pressing the sleeve against the skin and moving the barrel relative to the sleeve (e.g. as part of one movement in which the barrel is gripped and pressed, sleeve first, against the skin).

Because the penetration of the needle is controlled by the extent of movement of the components of the syringe, incorrect injection is less likely. Furthermore, because the gas generator itself causes the delivery of the drug, the speed and amount of delivery are predetermined and out of the control of the user. Automatic delivery also prevents needle injuries from occurring as a result of the user having to manipulate the syringe during the time when the needle is penetrating the skin.

Needle injuries are further prevented because the sleeve conceals the needle when in the first position. Not only does this prevent accidental injury, but it also addresses user compliance problems. It is the experience of many doctors and nurses that many patients are prepared to have injections administered but will close their eyes or turn their heads during injection. For such patients it is not the actual pain of injection, but rather the sight of the injection taking place or the sight of the needle itself, which causes distress.

In cases where a patient cannot watch an injection taking place, self-injection is not practical. The syringe according to the invention provides a solution, since not only does it allow the needle to remain invisible during delivery, but it allows the patient to self-inject without looking at the needle at all.

In contrast to needleless syringes, the syringe according to the present invention does not require a significant amount of pressure to deliver the drug as the needle pierces the outer layers of skin enabling the liquid drug to flow subcutaneously at relatively low pressure. As a result, the present invention does not require pre-pressurised chambers since a relatively simple gas generator creating a relatively low pressure can be employed. The syringe according to the present invention can be sold and safely stored for extended periods of time in a pre-filled condition which ensures sterility.

Because the present invention is automatically injected no priming is required on the part of the user, and correct depth of delivery is ensured consistently.

Suitably, the gas generator is disposed at an end of the reservoir distal from the needle, and wherein the relative movement of the sleeve and the barrel cases the gas generator to be compressed and thereby actuated.

The arrangement of the gas generator at the second end of the barrel provides a compact syringe, not significantly bigger than a conventional syringe. Indeed, the size of the syringe according to the invention may be significantly smaller than a conventional prefilled syringe having the same delivery volume. This is because in such syringes the plunger is extended before use, almost doubling the syringe length. Such size reductions are advantageous because storage costs and transportation costs are reduced and convenience increased.

Suitably, the gas generator comprises first and second chambers separated by a deformable membrane.

Preferably, the gas activation means comprises means for puncturing the deformable membrane.

In preferred embodiments, the gas activation means is activated by movement of the barrel and sleeve from the first position to the second position.

The advantage of the arrangement of the present invention is that the syringe operates to reliably inject a substance with the user being only required to press the barrel, sleeve first, towards the injection site. This single movement serves to penetrate the skin and activate the gas generator, causing the drug to be injected. Thus, the number of steps involved is not only fewer than in the prior art alternatives to conventional syringes, but also fewer even than for conventional pre-filled syringes.

With a pre-filled syringe, the user (or physician or nurse) must first penetrate the injection site with the needle, and second, depress the plunger to deliver the drug. Both of these steps may be relatively simple to a trained person, but they nevertheless each require considerable care. According to the present invention, however, the barrel can be grasped, pushed against the skin and removed after delivery. No other steps are required and no particular care needs to be taken because the automatic nature of the device removes the likelihood of user error.

Preferably, the sleeve is axially biased towards the first position so that it moves to the first position when no pressure is applied to the barrel.

This feature ensures that the needle is never visible to the user and obviates the need for the user to employ a retraction mechanism. This feature improves the safety of the syringe and reduces the likelihood of injury if the syringe is not disposed of properly.

Many healthcare workers accidentally prick themselves each year in hospitals and clinics throughout the world. Such accidents may result in the contraction of a fatal disease or considerable mental anguish associated with the possibility of contracting a fatal disease. As a result of these risks, hospitals and other healthcare providers are continually seeking ways to decrease the risk of injury associated with exposed, contaminated needles.

The present invention addresses this problem and reduces the risk of injury by employing syringes in which the needle is automatically retracted. Healthcare organisations and institutions could lower the occurrence of such injuries and also lower their liability for such claims against them by healthcare workers and significantly reduce injury and illness as well as insurance premiums.

Preferably, the sleeve is axially biased by means of a coil spring.

Further, preferably, the coil spring is disposed between the sleeve and the barrel. A coil spring disposed in this way does not add to the size of the syringe.

Preferably, the sleeve is torsionally biased. Such torsional biasing enables advantageous safety features to be achieved, as will be explained further below.

Suitably, the axial and torsional bias are provided by a compression-extension spring under torsional strain.

The compression-extension spring may be a coil spring disposed between the sleeve and the barrel. A coil spring disposed in this way does not add to the size of the syringe, but it adds the safety feature of a permanently concealed needle, and a safety locking mechanism as described below.

Preferably, the syringe further comprises locking means such that when the sleeve from returns from the second position to the first position the locking means prevents the sleeve from returning to the second position.

This feature provides a single use syringe which can be safely disposed of without fear of accidental injury. Even if not correctly disposed of, the fact that the sleeve becomes locked after use in the second

position means that the needle is permanently concealed by the sleeve to prevent accidental injury and to deter intentional re-use of the syringe.

Preferably, the locking means comprises a pair of co-operating formations disposed on the sleeve and the barrel respectively.

Further, preferably, the pair of co-operating formations comprises a slot and a member received in the slot respectively.

A suitably shaped slot has an angled portion which causes the rotational biasing to increase as the sleeve completes its travel from the second position back to the first position, and a horizontal portion (perpendicular to the axis of the barrel) which permits rotational relaxation when the sleeve has returned to the first position.

Preferably, the first and second chambers house the components of an effervescent couple respectively.

A large volume of gas can be generated from a relatively small quantity of solid or liquid effervescent reactants. Thus, the size of the gas generator can be significantly smaller than the volume of liquid to be delivered, and for this reason, the syringe according to the invention may be made of a size comparable to conventional syringes.

Preferably, at least one of the components of the couple is a liquid.

Further, preferably, the components of the effervescent couple are citric acid and sodium bicarbonate respectively.

The cost of an effervescent couple (such as citric acid and sodium bicarbonate) is relatively low and so the mechanism employed is extremely inexpensive compared to that of a compressed gas needleless injector.

Preferably, the needle extends between about 1-3 mm beyond the first end of the barrel.

Once the *stratum corneum* has been penetrated, subcutaneous delivery can be easily achieved. Thus, there is no necessity for a deep penetration.

Most preferably, the needle extends approximately 1 mm beyond the first end of the barrel.

Because the injection site is already stretched by the sleeve (to which pressure is applied in order to cause movement between the first and second positions), the syringe according to the invention enables a very small depth of penetration to be achieved. With conventional syringes, the natural elasticity of the skin makes it difficult to ensure a small penetration depth: the force applied to the needle tip in order to overcome the elasticity of the skin causes the needle to penetrate deeper than necessary once the skin is penetrated.

Another factor related to the penetration of the skin is the direction of penetration. In order to prevent excessive pain, the orientation of the needle into the skin should not vary at all. If there is any movement of the needle, the entry wound becomes enlarged.

The device according to the invention has a short needle which always penetrates at 90° to the skin surface against which the sleeve abuts. Because the skin is stretched by the sleeve, small movements of the barrel or changes in direction do not cause any movement of the stretched skin surface relative to the sleeve, and hence to the needle also.

Preferably the gas generator generates a pressure of about 2 atmosphere.

Such a pressure delivers a liquid at an acceptable rate into the tissue immediately below the epidermis.

The invention also provides a method of injecting liquid drug comprising the following steps:

a) providing a barrel having a liquid drug reservoir therein, a delivery needle mounted on the first end of the barrel,

b) locating a gas generator at the second end of the barrel, the gas generator in communication with the reservoir when the gas generator is activated, so as to drive a liquid from the reservoir through the needle;

c) resiliently mounting a sleeve within the first end of barrel, the sleeve capable of assuming a first position where the tip of the needle is concealed by the sleeve and a second position where the tip of the needle is revealed;

d) activating the gas generator;

e) placing the sleeve against an injection site; and

f) moving the barrel toward the injection site, thereby causing the sleeve to move from the first position to the second position, the needle to penetrate the injection site, and the gas generator to drive a liquid from the reservoir into the injection through the needle.

Preferably, the method according to the invention further comprises the step of causing the sleeve to return to the first position after moving to the second position.

Further, preferably, the method further comprises the step of preventing the sleeve from returning to the second position after returning to the first position.

The invention will be further illustrated by the following description of embodiments thereof, given by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a sectional view of a syringe according to the invention, illustrated as supplied to the user;

Fig. 2 is an exploded view of the syringe of Fig. 1;

Fig. 3 is a sectional view of the syringe of Fig. 1, with the needle cover removed;

Fig. 4 is a sectional view of the syringe of Fig. 1, shown as it is being applied to the injection site;

Fig. 5 is a sectional view of the syringe of Fig. 1, shown as the liquid is being injected;

Fig. 6 is a sectional view of the syringe of Fig. 1, shown after injection;

Figs. 7A-7D are sectional views of a detail of the syringe of Fig. 1, shown at successive stages corresponding to Figs. 3-6, respectively;

Fig. 8 is a perspective view of a spring used in the syringe of Fig. 1; and

Fig. 9 is a perspective view of the syringe of Fig. 1.

In Fig. 1 there is indicated, generally at 10, a syringe according to the invention which is shown in exploded view in Fig. 2. The syringe 10 comprises a barrel 11 containing an internal cylindrical body 12 in which a piston 13 is slidably inserted. A reservoir for a liquid 14 for injection is defined on one side of piston 13 within cylindrical body 12. A needle 15 is mounted on a mounting body 28 which joins the needle to a first end of the cylindrical body 12. The internal cylindrical body 12 communicates with the liquid 14 and enables delivery thereof under movement by the piston 13. For sterility the needle 15 is protected by a protective cover 16 before use.

A gas generator 17 is mounted within the barrel 11 at the opposite end of the cylindrical body 12 from the needle 15. The generator 17 is provided with a plug fitting 18 which is received by the cylindrical body 12. A displaceable sleeve 20 is mounted at the opposite, open end 19 of the barrel 11. The sleeve 20 has an aperture 21 through which the needle cover 16 protrudes before use. The sleeve 20 is movable from the first position shown in Figs. 1 and 2 by sliding upwards in the interior of barrel 11, as will be described further below. However, a coil spring 22 biases the sleeve 20 to the first position as shown in Fig. 1.

Fig. 2 shows a shaped slot 23 in the sleeve 20 which, when assembled, receives a peg 24 in the interior of the barrel 11. The shape of the slot 23 causes relative rotation between the barrel 11 and the sleeve 20 when they are moved axially relative to one another. This feature, which provides a safety locking mechanism, will be explained in greater detail below.

Fig. 3 shows the syringe 10 immediately before use. The needle cover 16 is removed by the user by pulling it away from the barrel 11 out of the aperture 21. It can be seen that even in this configuration, wherein the syringe 10 is ready for use, the needle 15 is concealed by the sleeve 20.

In order to use syringe 10, the sleeve 20 is placed against an injection site 25 as shown in Fig. 4, and barrel 11 is pushed against the injection site 25. The freedom of movement of the sleeve 20 enables the barrel 11 to move downwardly towards the injection site 25, with the sleeve 20 being received internally of the barrel 11. In Fig. 4, the syringe is shown just before the sleeve 20 has reached its limit of internal movement, i.e. just before the second position referred to above. At this point, the upper lip 26 of the sleeve 20 is abutting against a flange 27 of mounting body 28 which mounts the needle 15 on the cylindrical body 12. It can be seen that the needle 15 has penetrated the injection site 25.

The gas generator 17, however, has not yet been actuated. The gas generator 17 comprises an upper chamber 29 filled with citric acid solution

30 and a lower chamber 31 containing a mass of sodium bicarbonate 32 (other effervescent couples could of course be used). A lower chamber 31 communicates with a pumping chamber 33 in cylindrical body 12 defined between the gas generator 17 and the piston 13.

Upper chamber 29 is bounded by a penetrable laminated foil membrane 34. A cutting member 35 is provided in the lower chamber 31 so as to rest against the membrane 34. The membrane 34 must create a barrier between the upper and lower chambers 29,31 yet be penetrable. The upper and lower chambers 29,31 are connected together by a circumferential seal 36.

The upper chamber 29 is provided with a flexible peripheral portion 37 adjacent to the seal 36. Because of its flexibility, the peripheral portion 37 imparts a small amount of freedom of movement of upper chamber 29 towards lower chamber 31. Therefore, if the gas generator 27 is mechanically compressed, the upper chamber 29 moves towards the lower chamber 31 resulting in the penetration of the foil membrane 34 by the cutting member 35.

Downward pressure on the barrel 11 results in the situation shown in Fig. 5. The sleeve 20 pushes the flange 27 and hence the cylindrical body 12 and the gas generator 17 upwards within the barrel 11. When the gas generator 17 reaches the top of barrel 11 it is compressed. This compression causes cutting member 35 to penetrate foil membrane (not visible in Fig. 5), releasing citric acid 30 into contact with sodium bicarbonate 32. This results in the immediate generation of carbon dioxide causing the pumping chamber 33 to become pressurised, which in turn drives the piston 13 downwards to deliver the liquid 14 from cylindrical body 12 to the injection site 25 *via* the needle 15.

When delivery has been completed (this may suitably take of the order of 3-5 seconds, although longer or shorter times can be achieved if required), gas generation will generally not have been completed: a surplus of reactive gas generating materials is provided so as to ensure completion

of delivery. In order to prevent any dangerous pressure build up a release valve 38 is provided on the gas generator 17. The release valve 38 opens when pressure reaches a predetermined level. Thus, release valve 38 is also actuated by any blockage in delivery.

When delivery has been completed, the barrel 11 is removed from the injection site 25. As the pressure on the barrel 11 is relieved, the spring 22 pushes the sleeve 20 from the second position (Fig. 5) back to the first position (Fig. 6). Thus, the needle 15 is concealed even before the sleeve 20 has left the injection site 25. For severely needlephobic patients, any sight of the needle must be avoided if possible, and for safety reasons, it is highly preferable that the needle is never exposed. As a result of the slot 23 and the location of the peg 24 in the first position (as shown in Fig. 7D), the sleeve 20 is locked in the first position when it returns from the second position and the pressure of the spring 22 prevent it from returning to the second position, as will be discussed in more detail below.

Figs. 7A-7D illustrate the operation of the safety locking mechanism by showing the position of the peg 24 (mounted in the interior of barrel 11) in the slot 23 formed in the sleeve 20, at four stages of the delivery procedure, with Figs. 7A-7D corresponding to Figs. 3-6, respectively.

As indicated previously, the sleeve 20 is biased to the first position (Figs. 3 and 7A) by a coil spring 22, illustrated in Fig. 8. The ends of spring 22 form two outward projections 39, one of which engages barrel 11 and the other of which engages the sleeve 20. In addition to providing an axial biasing, spring 22 rotationally biases the sleeve 20 relative to the barrel 11 towards an equilibrium position, but the slot 23 and peg 24 constrain the relative rotation of the barrel 11 and the sleeve 20.

The equilibrium position is indicated in Figs. 7A-7D by a dotted line, which is the equilibrium position of the peg 24 in barrel 11 relative to the sleeve 20. Accordingly, in Figs. 7A-7C the peg 24 is to the left of the relaxed equilibrium position (in the view shown), resulting in a rotational bias of the sleeve 20 relative to the barrel 11 which would cause the peg to

move to the right. In Fig. 7D, the peg is effectively at the equilibrium position.

As the peg 24 is constrained in the slot, it has to follow the path illustrated in Figs. 7A-7C as the sleeve moves from the first position (Fig. 7A) to the second position (Fig. 7C). When delivery is completed and the pressure on the barrel is released, the sleeve is axially moved from the second position (Fig. 7C) to the first position. The rotational biasing of the spring 22, however, causes the peg 24 to travel into the right-hand arm 40 of the slot 23 (Fig. 7C), rather than the left-hand arm 41 in which it started. When the sleeve 20 has moved most of the way back towards the first position (just before the point illustrated in Fig. 7D), the peg 24 is biased to move leftwards (as seen in the view of Figs. 7A-7D) and passes the top right-hand corner 42 of the slot 23. At this point the peg is free to move leftwards, and thus it springs to the position shown in Fig. 7D, i.e. the barrel 11 and the sleeve 20 rotate relative to one another under the influence of the spring 22 to reach the Fig. 7D position.

When the peg 24 is in the position shown in Fig. 7D it is effectively trapped, and any attempt to move the sleeve 20 axially relative to the barrel 11 results in the peg 24 being stopped in the small notch 43. Accordingly, after a single reciprocation from the first position to the second position and back to the first position, the sleeve 20 is locked and the needle 22 is permanently concealed.

Fig. 9 shows the syringe 10 in perspective view before use. Thus, barrel 11, sleeve 20, and needle cover 16 can be seen. Also visible are slot 23 and the position of pin 24. A further feature is a transparent window 44 which allows the user to see when the delivery of liquid is complete so that the syringe 10 can be removed.

The needle 15 is preferred to extend from the sleeve by 1-3 mm, most preferably by 1 mm in length. In addition the ratio of citric acid to sodium bicarbonate in the gas generator should be sufficient to preferably generate a delivery pressure of approximately 2 atmospheres. This enables

the syringe 10 to deliver the liquid 14 to the user automatically at a low pressure and with a reduced risk of injury.

It will be appreciated that the embodiments discussed above are preferred embodiments, falling within the scope of the appended claims, and that various alternative embodiments are contemplated.

For example, other chemically reactive materials other than citric acid and sodium bicarbonate may be used in connection with the gas generator of the present invention. Other mechanisms other than the coil spring 22 may be used to exert upward pressure on the barrel 11 and activate the gas generator 17. Such alternative mechanisms include the use of any elastic or resilient member.

Claims: -

1. A syringe comprising:

a) a barrel having a liquid drug reservoir therein;

b) a delivery needle mounted on the first end of the barrel;

c) a gas generator located at the second end of the barrel, the gas generator in communication with the reservoir when the gas generator is activated, so as to drive a liquid from the reservoir through the needle;

d) gas generation activation means; and

e) a sleeve resiliently mounted on the first end of the barrel between a first position where the tip of the needle is concealed by the sleeve to a second position where the tip of the needle is revealed,

f) whereby when the sleeve is placed against an injection site and the barrel is moved toward the injection site, the sleeve is caused to move from the first position to the second position, and the needle is caused to penetrate the injection site, such that activation of the gas generator drives a liquid from the reservoir into the injection site through the needle.

2. The syringe of Claim 1 wherein the gas generator comprises first and second chambers separated by a deformable membrane.

3. The syringe of Claim 2 wherein the gas activation means comprises means for puncturing the deformable membrane.

4. The syringe of Claim 1 wherein the gas activation means is activated by movement of the barrel and sleeve from the first position to the second position.

5. The syringe of Claim 1 wherein the sleeve is axially biased towards the first position so that it moves to the first position when no pressure is applied to the barrel.

6. The syringe of Claim 5 wherein the sleeve is axially biased by means of a coil spring.

7. The syringe of Claim 6 wherein the coil spring is disposed between the sleeve and the barrel.

8. The syringe of Claim 5 wherein the sleeve is torsionally biased.

9. The syringe of Claim 8 wherein the axial and torsional bias are provided by a compression-extension spring under torsional strain.

10. The syringe of Claim 1 further comprising locking means such that when the sleeve returns from the second position to the first position the locking means prevents the sleeve from returning to the second position.

11. The syringe of Claim 10 wherein the locking means comprises a pair of co-operating formations disposed on the sleeve and the barrel respectively.

12. The syringe of Claim 11 wherein the pair of co-operating formations comprises a slot and a member received in the slot respectively.

13. The syringe of Claim 2 wherein the first and second chambers house the components of an effervescent couple respectively.

14. The syringe of Claim 13 wherein at least one of the components of the couple is a liquid.

15. The syringe of Claim 13 wherein the components of the effervescent couple are citric acid and sodium bicarbonate respectively.

16. The syringe of Claim 1 wherein the needle extends between about 1-3 mm beyond the first end of the barrel.

17. The syringe of Claim 1 wherein the needle extends approximately 1 mm beyond the first end of the barrel.

18. The syringe of Claim 1 wherein the gas generator generates a pressure of about 2 atmosphere.

19. A method of injecting liquid drug comprising the following steps:

a) providing a barrel having a liquid drug reservoir therein, a delivery needle mounted on the first end of the barrel,

b) locating a gas generator at the second end of the barrel, the gas generator in communication with the reservoir when the gas generator is activated, so as to drive a liquid from the reservoir through the needle;

c) resiliently mounting a sleeve within the first end of barrel, the sleeve capable of assuming a first position where the tip of the needle is concealed by the sleeve and a second position where the tip of the needle is revealed;

d) activating the gas generator;

e) placing the sleeve against an injection site; and

f) moving the barrel toward the injection site, thereby causing the sleeve to move from the first position to the second position, the needle to penetrate the injection site, and the gas generator to drive a liquid from the reservoir into the injection through the needle.

20. The method of Claim 19 further comprising the step of causing the sleeve to return to the first position after moving to the second position.

21. The method of Claim 20 further comprising the step of preventing the sleeve from returning to the second position after returning to the first position.

22. The method of Claim 19 wherein the gas generator comprises a first chamber and a second chamber separated by a deformable membrane.

23. The method of Claim 22 wherein the first and second chambers house the components of an effervescent couple respectively.

24. The method of Claim 23 wherein at least one of the components of the couple is a liquid.

25. The method of Claim 23 wherein the components of the effervescent couple are citric acid and sodium bicarbonate respectively.

26. The method of Claim 22 the gas generator is activated by piercing the membrane.

27. The method of Claim 19 wherein the needle penetrates the injection site about 1-3 mm.

28. The method of Claim 19 wherein the pressure within the gas generator is about 2 atmosphere.

Abstract

A syringe comprises a barrel containing an internal cylindrical body containing a liquid and communicating with a delivery needle. The needle is covered before use by a removable sheath, and after the sheath is removed, the needle is concealed by a displaceable sleeve. In use the sleeve is pressed against the skin by applying pressure while holding the barrel. The sleeve is thereby retracted into the barrel allowing the needle to penetrate the skin. The movement of the sleeve also activates a gas generator which expels the liquid from the needle. When delivery is complete and the syringe is taken from the skin, a coil spring moves the sleeve back to the starting position again concealing the needle. The coil spring is torsionally biased before use and causes a rotational movement of the sleeve relative to the barrel when the sleeve moves into and out of the barrel. This rotational movement engages a locking mechanism which prevents further movement of the sleeve and thereby permanently conceals the needle.

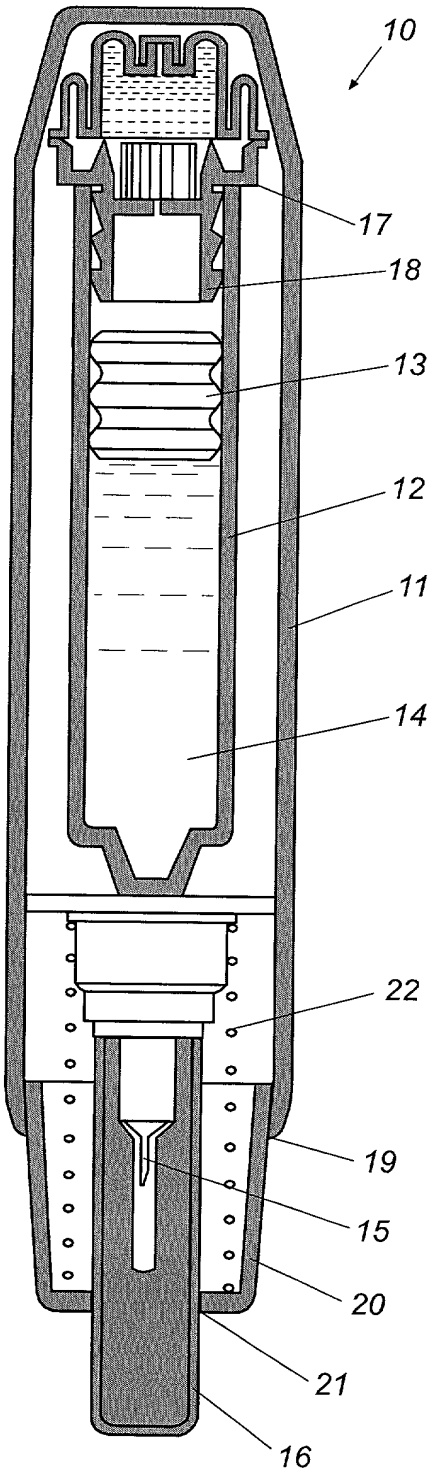
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Fig. 1

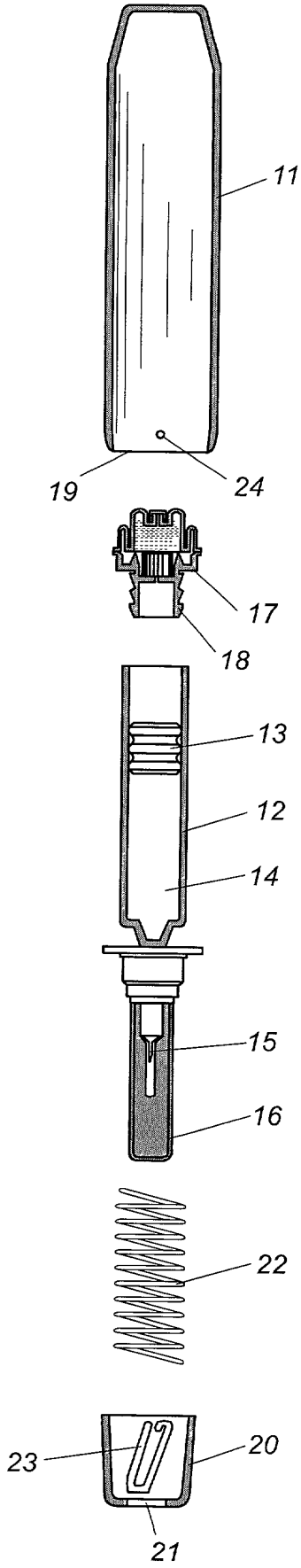
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Fig.2

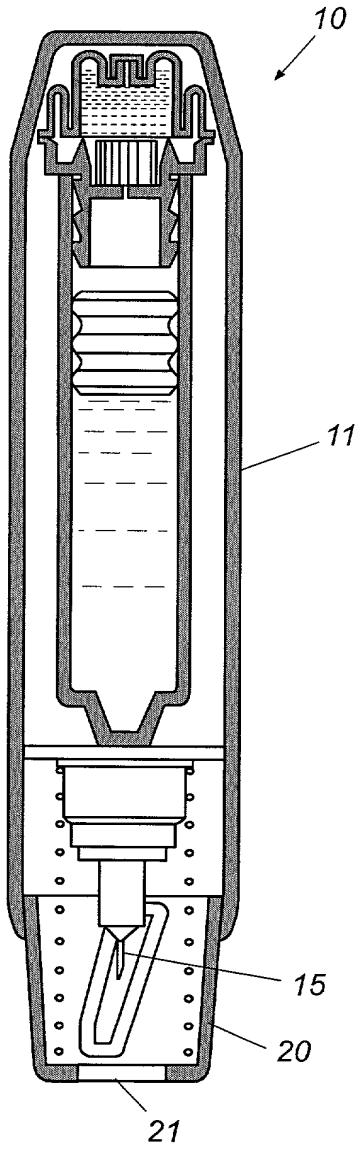

Fig. 3

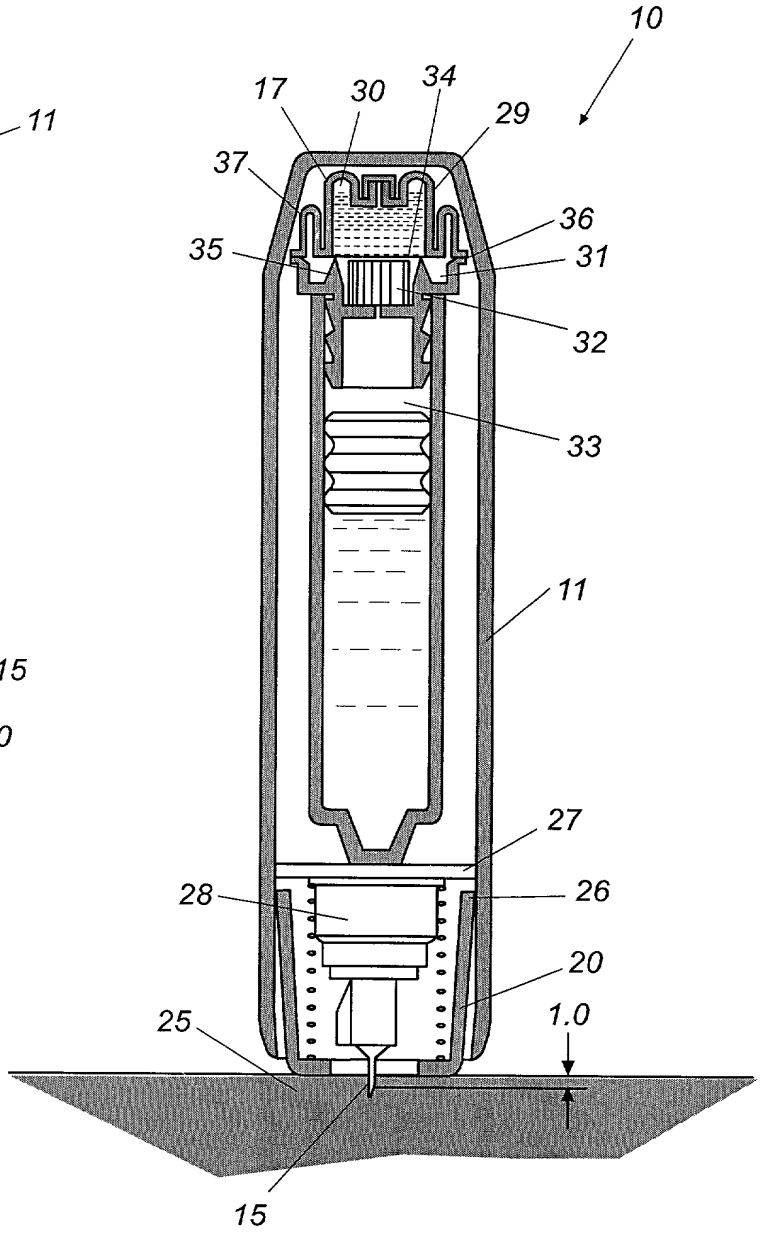

Fig. 4

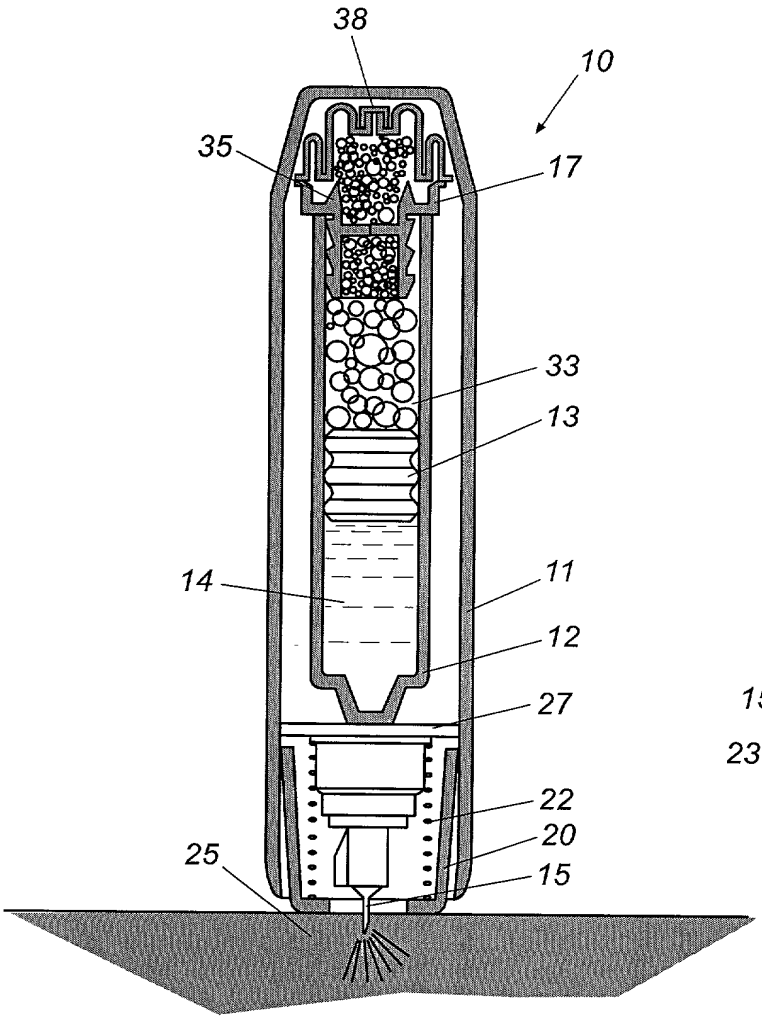

Fig. 5

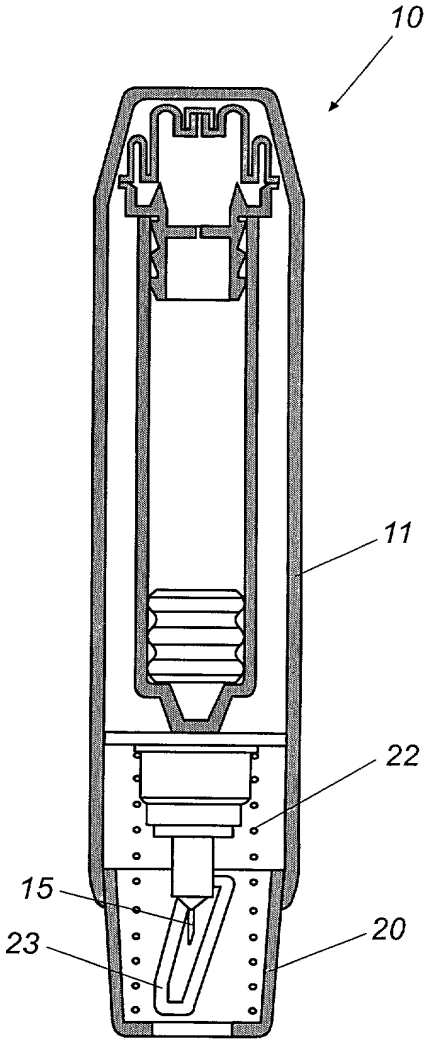

Fig. 6

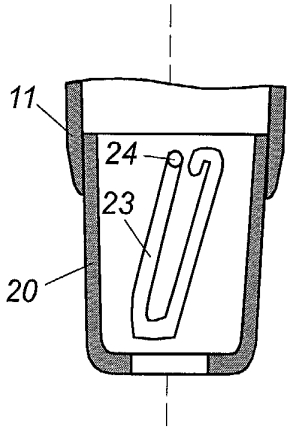

Fig. 7A

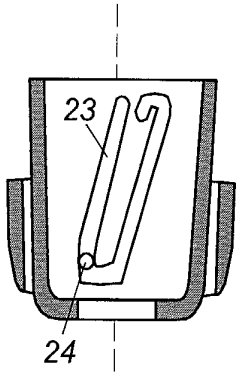

Fig. 7B

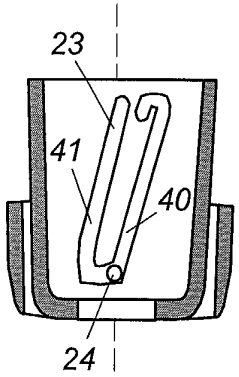

Fig. 7C

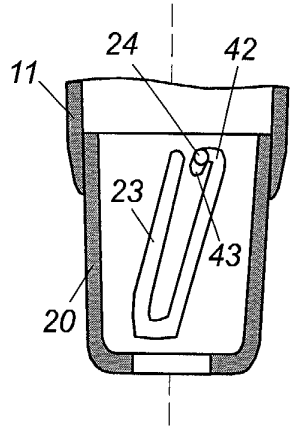

Fig. 7D

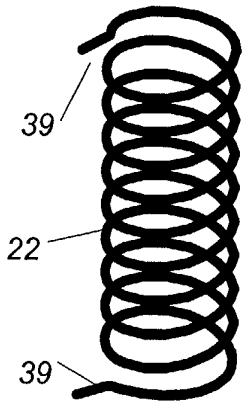

Fig. 8

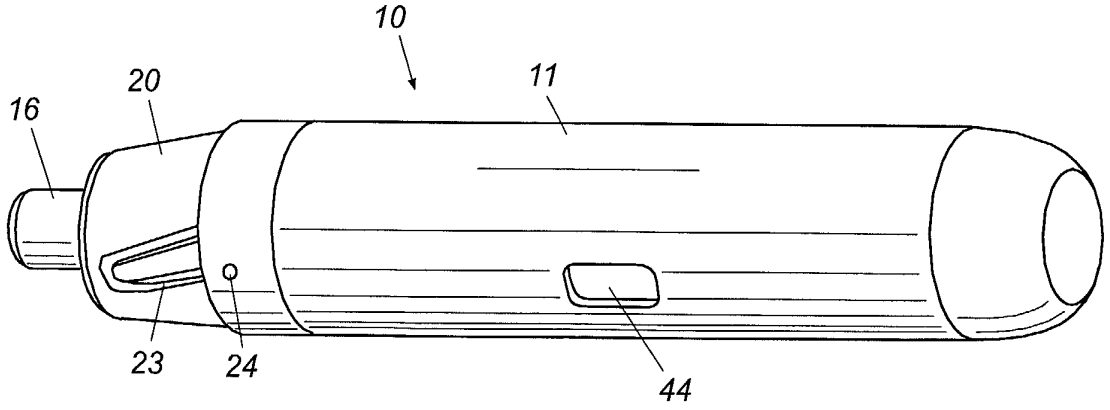

Fig. 9

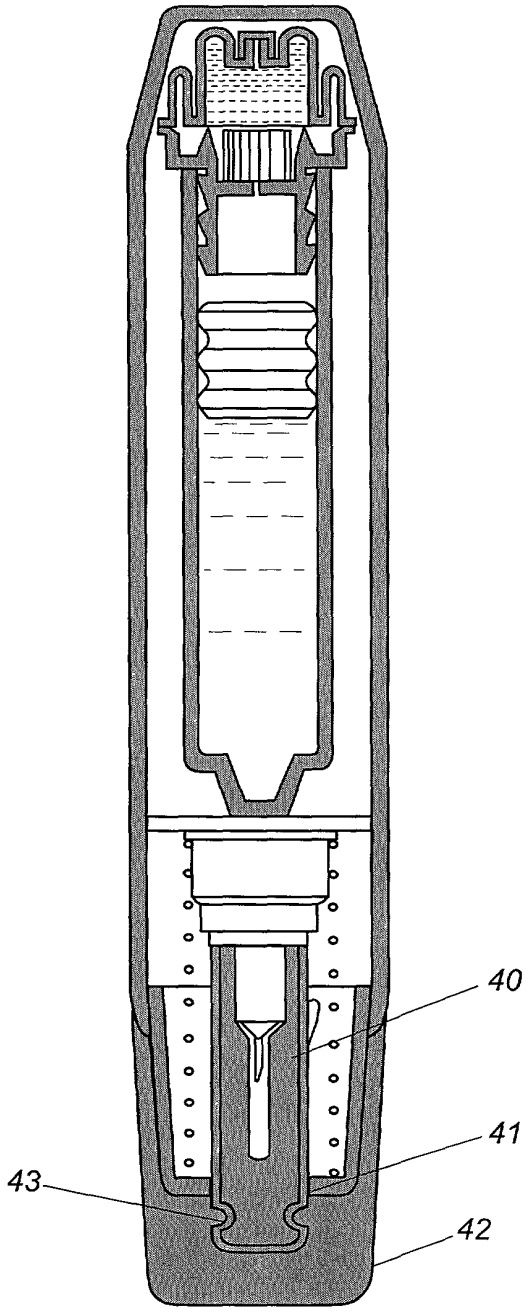

Fig. 10

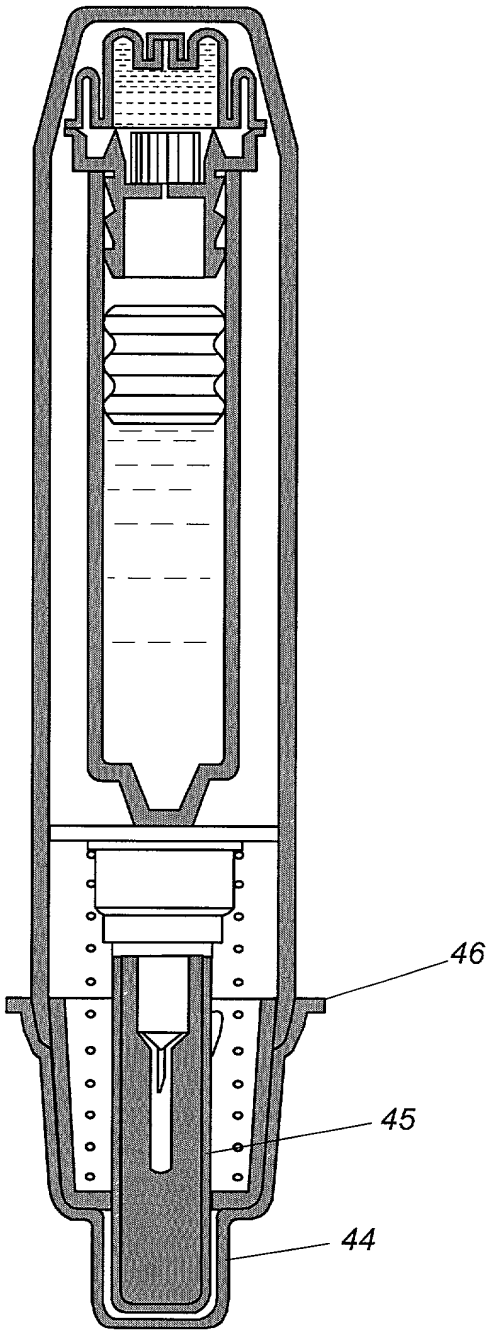

Fig. 11

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

(x) Original ( ) Supplemental ( ) Substitute ( ) PCT

This copy of the Declaration is intended for the attached Application submitted herewith (Continuation of Application Serial No. 09/176,439)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled **"Pre-filled Injection Device"**, the specification of which:

(check one) [ ] is attached hereto, or
[X] was filed on **October 21, 1998**, and assigned serial number **09/176,439**
[ ] was described and claimed in PCT International Application No._____,
filed _____, and as amended on _____(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information known by me to be material to the patentability of the claims of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT International application(s) designating at least one country other than the United States of America filed by me or relating to this subject matter having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATIONS: (ENTER BELOW IF APPLICABLE)			PRIORITY CLAIMED (MARK APPROPRIATE BOX BELOW)	
APP. NUMBER	COUNTRY	DAY/MONTH/YEAR FILED	YES	NO
970,782	Ireland	07/11/97	✓	

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER	FILING DATE
08/956,237*	22/10/97

*Regular application converted to provision on 20 October, 1998.

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT International application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information known by me to be material to the patentability of the claims of this application as defined in Title 37, Code of Federal Regulations, §1.56 which became

available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

APP. SER. NO.	FILING DATE	STATUS (MARK APPROPRIATE COLUMN BELOW)		
		PATENTED	PENDING	ABANDONED

I hereby appoint the following attorneys and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Marla J. Church, (Reg. No. 29,908);
Mary L. Severson (Reg. No. 34,927); and
Kathleen L. Maher (Reg. No. 33,957).

Address all telephone calls to Kathleen L. Maher at telephone no. (770) 534-8239.

Address all correspondence to: Kathleen L. Maher
Elan Pharmaceutical Research Corp.
1300 Gould Drive
Gainesville, GA 30504

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: **Joseph Gross.**
Inventor's signature: _____
Date: 7 DECE. 98 Residence: **Moshav Mazor, Israel 20502, Israel.**
Citizenship: **Israel.**
Post Office Address: **SAME AS RESIDENCE**

Full name of second inventor: **Gilad Lavi.**
Inventor's signature: _____
Date: 7 DEC. '98 Residence: **Bazov David No. 6, K. Sharet, Holon 58497, Israel.**
Citizenship: **Israel.**
Post Office Address: **SAME AS RESIDENCE**

Full name of third inventor: **Izrail Tsals.**
Inventor's signature: _____
Date: Dec 15 98 Residence: **17 Rose Way, Sudbury, Massachusetts, 01776 U.S.A.**
Citizenship: **U.S.A.**
Post Office Address: **SAME AS RESIDENCE**

ATTORNEY DOCKET NO. 00.EMT 34(c).US (E1067/20007) **U.S. PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	ÉLAN CORPORATION, plc.
Continuation of U.S. Application No.	:	09/176/439
For	:	AN IMPROVED AUTOMATIC SYRINGE

POWER OF ATTORNEY BY ASSIGNEE

Commissioner of Patents and Trademarks
ATTN: OFFICE OF PUBLIC RECORDS DISSEMINATION SUPPORT DIVISION
North Tower 10B10
Washington, D.C. 20231

Sir:

ÉLAN CORPORATION, plc., Assignee of the entire right, title and interest in U.S. Patent Application Serial No. 09/176,439 filed October 21, 1998 by virtue of Assignment recorded at Reel 9724, Frame 0621, of the Patent Office microfilm records, hereby revokes all prior powers of attorney and appoints the following as attorneys of record with full power of substitution and revocation to prosecute the identified application and all continuations and divisions thereof, and to transact all business in the Patent and Trademark Office, including the payment of maintenance fees for the identified patent and any patents issuing on the identified application and their progeny:

Alan H. Bernstein, Registration No. 19,315;
Stanley H. Cohen, Registration No. 20,235;
Manny D. Pokotilow, Registration No. 22,492;
Barry A. Stein, Registration No. 25,257;
Martin L. Faigus, Registration No. 24,364;
Eric S. Marzluf, Registration No. 27,454;
Robert S. Silver, Registration No. 35,681;
Michael J. Berkowitz, Registration No. 39,607;
Scott M. Slomowitz, Registration No. 39,032;
David M. Tener, Registration No. 37,054
James J. Kozuch, Registration No. 39,733
Francis M. Linguiti, Registration No. 32,424
Gary A. Greene, Registration No. 38,897
Marilou E. Watson, Registration No. 42,213
Michael J. Cornelison, Registration No. 40,395
Christopher M. Marrone, Registration No. 45,101

ALL CORRESPONDENCE IN CONNECTION WITH THIS APPLICATION SHOULD BE SENT TO **BARRY A. STEIN**, CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD., 12TH FLOOR, SEVEN PENN CENTER, 1635 MARKET STREET, PHILADELPHIA, PENNSYLVANIA 19103-2212. TELEPHONE: (215)567-2010.

The evidentiary documents have been reviewed, and the undersigned hereby certifies that, to the best of assignee's knowledge and belief, title is in the aforesaid assignee. The undersigned also certifies that the undersigned is empowered to execute this Power of Attorney on behalf of the assignee.

Pursuant to M.P.E.P. § 402, the original of this paper is being filed in the above-captioned patent and accordingly will be available for inspection by the public in at least that patent file.

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; and further, these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

11 July 2000
Date


Signature

Typed Name: William F. Daniel

Title: Assistant Company Secretary